



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/566,448 | 04/18/2006 | Luke Alphey | 7-06 | 1911 |
| 23713 7590 08/29/2008 GREENLEE WINNER AND SULLIVAN P C 4875 PEARL EAST CIRCLE SUITE 200 BOULDER, CO 80301 | | | | |
| EXAMINER | | | | |
| SGAGIAS, MAGDALENE K | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1632 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 08/29/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,448

Applicant(s)

ALPHEY, LUKE

Examiner

MAGDALENE K. SGAGIAS

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/8/08.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The previous restriction requirement has been vacated and a new restriction requirement is set forth below.

Claims 1-42 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) **1-21, 23-25, 29-30, 33-35, 26-27** drawn to an insect gene expression system, comprising at least one gene to be expressed and at least one promoter therefor, wherein a product of a gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and whereby the product, or the expression of the product, is controllable.

Group II, claim(s) **22**, drawn to an insect gene expression system, comprising at least one gene to be expressed and at least one promoter therefor, wherein a product of a gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and whereby the product, or the expression of the product, is controllable, wherein the effector gene encodes RNAI.

Group III, claim(s) **28**, drawn to an insect gene expression system, comprising at least one gene to be expressed and at least one promoter therefor, wherein a product of a gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and whereby the product, or the expression of the product, is controllable, wherein expression of the positive control gene on removal of a suppressor for the gene has substantially no effect on the fitness of an adult from which the suppressor has been removed.

Group IV, claim(s) **31**, drawn to an insect gene expression system, comprising at least one gene to be expressed and at least one promoter therefor, wherein a product of a gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and

whereby the product, or the expression of the product, is controllable, wherein said vector is pLA513 as identified by SEQ ID NO. 16.

Group V, claim(s) **32**, drawn to an insect gene expression system, comprising at least one gene to be expressed and at least one promoter therefor, wherein a product of a gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and whereby the product, or the expression of the product, is controllable, wherein said vector is JY2004-tTA as identified by SEQ ID NO. 14.

Group VI, claim(s) **36**, drawn to an insect gene expression system, comprising at least one gene to be expressed and at least one promoter therefor, wherein a product of a gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and whereby the product, or the expression of the product, is controllable, further comprising an expressible transposase gene.

Group VII claim(s) **37-41**, drawn to an insect comprising in its genome, an insect gene expression system, comprising at least one gene to be expressed and at least one promoter therefor, wherein a product of a gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and whereby the product, or the expression of the product, is controllable.

Group VIII, claim(s) **42**, drawn to a method to establish compatibility of a promoter with a species, comprising transforming said species with a plasmid, or other vector, comprising the system according to an insect comprising in its genome, the system according to an insect gene expression system, comprising at least one gene to be expressed and at least one promoter therefor, wherein a product of a gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and whereby the product, or the expression of the product, is controllable with the promoter to be tested, said promoter being operably associated with a gene to be assayed, said plasmid further comprising a marker, under the control of a promoter appropriate to said species, the method further comprising assaying putative transgenic individuals for expression of the marker, and wherein individuals expressing the marker are subsequently assayed for expression of the gene to be assayed.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Horn et al, [Nature, 21: 64-70, 2003 (IDS)] disclose a transgene-based, embryo-specific lethality system for insect pest management, comprising of hypereactive pro-apoptotic gene to be

expressed and at least one promoter, wherein a product of the gene to be expressed serves as a positive transcriptional control factor for the at least one promoter, and whereby the product, or the expression of the product, is controllable. The Horn reference renders claim 1, among the others not novel. Thus, the technical feature of the insect gene expression system is not special and the groups are not so linked under PCT Rule 13.1. Further, the compositions of groups II-VIII are distinct from the insect gene expression system of group I as they are physically and functionally distinct insect gene expression systems, which share neither structure nor function. Additionally, the claimed method in group VIII has distinct method steps, produce different products and/or different results, which are not coextensive and which do not share the same technical feature.

Upon election of any one of group I-VIII, Applicant is required to make the following additional election, of species.:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A) Currently, this application contains claims 1-42 generic to a plurality of disclosed patentably distinct species comprising hsp70, a P minimal promoter, a CMV minimal promoter, an Act5C-based minimal promoter, a BmA3 promoter fragment, an Adh core promoter, and an Act5C minimal promoter. B) Currently, this application contains claim 26 generic to a plurality of disclosed patentably distinct species comprising one cistron or more than one cistron. C) Currently, this application contains claim 27 generic to a plurality of disclosed patentably distinct species comprising two cistrons or more than two cistron.

Applicant is required under 35 USC 121 to elect a single species, even though this requirement is traversed.

Should Applicant traverse on the grounds that the species are not patentably distinct, Applicant should submit evidence or identify such evidence of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAGDALENE K. SGAGIAS whose telephone number is (571)272-3305. The examiner can normally be reached on 8.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Magdalene K. Sgagias, Ph.D.
Art Unit 1632

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632